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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 10 1986

MEMORANDUM

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: IR-4 Proposal to establish tolerances for Iprodione and its isomer and metabolite(s) in or on ginseng.

TO: Hoyt Jamerson, PM 43
Emergency Response and Minor Use Section
Registration Support and Emergency Response Branch
Registration Division (TS-767)

FROM: Margaret L. Jones *M. L. Jones 9/9/86*
Review Section III
Toxicology Branch, HED
(TS-769)

THROUGH: Marcia Van Gemert, Ph.D., Head *M Van Gemert 9.9.86*
Review Section III
and Theodore M. Farber, Ph.D, Chief
Toxicology Branch *WJ Jamerson 9.9.86*

Compound: Iprodione; Rovral; Glyphophene Tox. Chem. No: 470A

Record No: 176364, 176366 Tox. Project No: 2136

Petitioner: Interregional Research Project No. 4

Accession No: 263586, 263748 Petition No: 6E3426, 6H5504

Action Requested: Establish tolerances for Iprodione and its isomer and metabolite in or on the raw agricultural commodity ginseng at 2 ppm and in or on the commodity ginseng at 4 ppm.

Data Considered:

- Reproduction in the rat (undated)
- Chronic/oncogenicity in the mouse (3/6/78)
- Subchronic dog (undated)
- Developmental toxicity in the rabbit (12/12/85)

Data Currently Lacking on Iprodione: Toxicology data requirements were published in the Federal Register (Vol.49 No.207, 10/24/84, pp. 42892-42893). According to these requirements, the following data for the technical chemical are lacking:

Acute dermal LD50

1/4

Dermal sensitization
Developmental toxicity in a species other than the rabbit
General metabolism

Actions Under Way to Obtain Missing Data: No known action is presently under way to obtain these data.

Published Tolerances for Iprodione: Tolerances exist for Iprodione in or on raw agricultural commodities as published in 40 CFR 180.399, 21 CFR 193.251, and 21 CFR 561.263.

Effect of Proposed Tolerance on Acceptable Daily Intake (ADI):
The present request for tolerances of Iprodione in or on ginseng at 4 ppm was analyzed in a Toxicology Branch ADI Printout (copy attached). The acceptable daily intake is based on the three generation reproduction study in rats with a no observed effects level of 500 ppm (25 mg/kg/day). The cumulative percent of the ADI used from the existing and proposed actions is 13.0068 for the U.S. population.

Acceptable Daily Intake, Maximum Permissible Intake, and Theoretical Maximum Residue Contribution:

ADI = 0.25 mg/kg/day
MPI = 15 mg/kg/day (60 kg person)
TMRC = 0.033 mg/kg/day
NOEL = 500 ppm (25 mg/kg/day)
Safety Factor = 100

Recommendation: Toxicology Branch recommends approval of the proposed tolerance for Iprodione in or on ginseng at 4 ppm. We again recommend taking steps to obtain the currently lacking toxicity data on Iprodione

Glycophene (Iprodione)

ADI = 0.250000 mg/kg/day

Caswell #470A

NOEL = 0.0000 mg/kg

Safety Factor = 100

CFR No. 180.399

LEL = 0.0000 mg/kg

Status: ADI NOT VERIFIED BY TOX ADI COMMITTEE OR AGENCY RFD COMMITTEE.

RESIDUE CONTRIBUTION OF PUBLISHED TOLERANCES

CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
1 Almonds	0.050		0.03	0.000023
54 Eggs	0.800		2.77	0.033240
61 Garlic	0.100		0.03	0.000045
67 Grapes, not including raisins	60.000		0.45	0.405000
84 Lettuce	15.000		1.31	0.294750
90 Meat, red	0.400		10.81	0.064860
93 Milk and dairy products	0.300		28.62	0.128790
128 Poultry	2.000		2.94	0.088200
134 Raisins	300.000		0.04	0.180000
151 Stone fruits	20.000		1.25	0.375000
203 Kidney	3.000		0.03	0.001350
204 Kiwi fruit	10.000		0.03	0.004500
211 Liver	3.000		0.03	0.001350

TMRC

0.026285 mg/kg/day (60kg BW, 1.5kg diet)

%ADI

10.514050

RESIDUE CONTRIBUTION OF TOX-APPROVED TOLERANCES

CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
1 Almonds	0.250	5F3241	0.03	0.000112500
10 Beans, dry edible	4.000	4F3150	0.31	0.018600000
11 Beans, lima	2.000	4F3150	0.19	0.005700000
12 Beans, snap	2.000	4F3150	0.98	0.029400000
17 Boysenberries	15.000	4F3129	0.03	0.006750000
18 Blueberries	15.000	5E3214	0.03	0.006750000
19 Broccoli	25.000	6F3305	0.10	0.037500000
48 Currants	15.000	5E3214	0.03	0.006750000
90 Meat, red	0.200	4F3129	10.81	0.032430000
93 Milk and dairy products	0.400	4F3129	28.62	0.171720000
105 Onions	0.500	4F3111	0.83	0.006225000
115 Peanuts	0.100	4G3037	0.36	0.000540000
115 Peanuts	0.400	4F3129	0.36	0.002160000
127 Potatoes	0.500	6F3366	5.43	0.040725000

RESIDUE CONTRIBUTION OF TOX-APPROVED TOLERANCES

CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
135 Raspberries	15.000	5E3214	0.03	0.006750000

TMRC
0.032487 mg/kg/day (60kg BW, 1.5kg diet)

%ADI
12.994800

RESIDUE CONTRIBUTION OF NEW (PENDING) TOLERANCES

CROP	TOLERANCE (PPM)	PETITION NUMBER	FOOD FACTOR	MG/DAY
223 Ginseng	4.000	6E3426	0.03	0.001800000

TMRC
0.032517 mg/kg/day (60kg BW, 1.5kg diet)

%ADI
13.006800
